



## Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



March 31, 2023 | Issue 265

### Editor's note

*This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. Please share this email with colleagues and other interested individuals, and encourage them to [subscribe to our mailing list here](#).*

We welcome your feedback. Let us know if KPMG can help. Please [reply here to me](#), **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.

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### Healthcare regulatory news

FDA [approved the first over-the-counter naloxone](#) spray... FDA will [convene an advisory panel to review](#) an ALS cell therapy that it previously refused to consider... FDA [guidance](#) delays enforcement to October for [medical device manufacturers to meet new cybersecurity requirements](#).

FDA draft [guidance recommended](#) oncology drug developers use a single randomized controlled trial [to seek accelerated approval](#) and confirm clinical benefit... FDA [draft guidance](#) streamlines updates to AI-enabled medical devices.

HRSA is [seeking compliance data from several 340B hospitals](#).

HHS [announced \\$123.6M in funding](#) to expand behavioral health clinics.

CMS [approved NJ's extended/amended section 1115 demonstration](#) to provide [housing and nutrition benefits](#) to Medicaid beneficiaries.

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## Healthcare law and policy news

A [federal judge struck down](#) the ACA requirement for coverage without cost sharing of USPSTF-recommended preventive services.

NC [enacted legislation making it the 40<sup>th</sup> state](#) to expand Medicaid... Oklahoma became the [30<sup>th</sup> state plus DC to offer one year of postpartum](#) Medicaid coverage.

The Supreme Court [heard arguments](#) in the *Amgen v. Sanofi* [patent dispute](#)... Ohio's Attorney General [sued Cigna/Express Scripts, Prime Therapeutics, Humana, and others](#) for [allegedly colluding](#) to "illegally drive up drug prices"... LabCorp will [pay \\$2.1M to settle FCA allegations](#) for overbilling the Defense Department.

CVS completed its [acquisition of Signify Health](#)... DOJ and FTC [did not take action to block](#) the CVS-Oak Street merger... Sartorius [will acquire Polyplus](#) (\$2.6B)... [UnitedHealthcare](#) and [Cigna](#) are reducing prior authorization requirements... Amazon Pharmacy [will automatically apply drug manufacturer coupons](#) directly to brand-name medication orders.

Altarum reported [healthcare employment has returned to February 2020 levels](#), although shortages remain for nursing and residential care employment... FAIR Health [reported telehealth utilization declined 76%](#) from 2020 to 2021, while utilization at retail clinics increased 51%.

A [Holon Solutions survey found 77% of healthcare workers](#) are experiencing burnout and 51% believe their job has gotten more difficult in the past year... A KFF poll found [81% of adults are worried](#) "that Medicare will not be able to continue to provide at least the same level of benefits in the future."

Senate Finance Committee [held a hearing on the impact of PBMs](#) on patients and taxpayers... House Energy and Commerce Health Subcommittee [held a hearing on transparency and competition](#) in healthcare.

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## Special Section: COVID-19 News

President Biden [does not plan to veto a resolution](#) to end the COVID-19 national emergency early; the public health emergency (PHE) is still set to expire on May 11.

FDA guidance documents state that: (1) manufacturers of COVID-19 tests and other devices granted emergency use authorization (EUA) [will be given approximately 180 days' notice](#) before the EUA is terminated; and, (2) devices that fall within certain enforcement polices, such as ventilators and personal protective equipment, will be [withdrawn within 180 days of the end of the public health emergency](#).

The Biden Administration [reported that the Public Health Emergency Medical Countermeasures Enterprise](#), which includes the Strategic National Stockpile and BARDA, NIH, and FDA countermeasure efforts, will [need \\$64B in funding over the next five years](#), but is underfunded by about \$35.3B.

A [CDC-CMS-NIH study found](#) patients receiving telehealth drug therapy for opioid use disorder during the pandemic (between September 2019 and February 2021) had 33% lower adjusted odds of a fatal overdose than those not receiving treatment.

A [Morning Consult-de Beaumont Foundation poll found](#) 72% of US doctors believe misinformation has made it harder to treat COVID-19 patients and harmed patient outcomes... Trust for America's Health [reported](#) nine states improved their public health preparedness in 2022, while nine states' preparedness fell.

Johnson & Johnson will [stop work on its investigational RSV adult vaccine program](#) and discontinue the Phase III trial.



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